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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,630	07/19/2001	Ming-Fong Lin	UNMC.63131US	7143

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EXAMINER	
CHAKRABARTI, ARUN K	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 10/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/889,630	LIN, MING-FONG	
	Examiner	Art Unit	
	Arun Chakrabarti	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-21* is/are pending in the application.

4a) Of the above claim(s) *1-13 and 22-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action* .

DETAILED ACTION

Specification

1. Applicant's election of claims 14-21 corresponding to Group III, without traverse, in Paper NO: 4, and CRF in Paper NO; 7 are hereby acknowledged. Applicant is hereby informed that the Paper NO:7 including amendment and CRF is still non-responsive to the office action (Paper NO:5) mailed on January 22, 2002 because the applicant inadvertently overlooked the requirement of a SEQ ID Number in claim 21. Appropriate correction and amendment is suggested.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 is rejected over the recitation of the phrase, "Northern, and Southern". It is not clear if the Northern blot and Southern blot analysis (as mentioned in the specification, page 27, lines 7-8) are claimed or the Northern, and Southern directions are claimed or both of them are claimed. The metes and bounds of the claims are vague and indefinite.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Provari et al. (Biochemical and Biophysical Research Communication, (August 24, 1995) (Vol. 213(3), pages 861-868) in view of Horoszewicz (U.S. Patent 5,763,202) (June 9, 1998).

Provari et al teach a method of determining the expression of cellular PAcP protein which is androgen-insensitive in the prostate (Abstract and Materials and Methods Section).

Provari et al teach a method, wherein the activity of cellular Pacp is quantified by measuring acid phosphatase activity and quantifying the concentration of cellular PacP mRNA by Northern blot analysis.(Figure 1 and Materials and Methods Section and Results section).

Provari et al do not teach a method, wherein prostate carcinoma is diagnosed comprising the step of determining the expression of cellular protein in the prostate carcinoma by quantifying a protein by an antibody immunologically specific to the cellular protein.

Horoszewicz teach a method, wherein prostate carcinoma is diagnosed comprising the step of determining the expression of cellular protein in the prostate carcinoma by quantifying a

protein by an antibody immunologically specific to the cellular protein (Abstract and Tables 1 and 2 and claims 1-14 and Column 9, line 40 to column 24, line 17).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine, within the method of Provari et al., method wherein prostate carcinoma is diagnosed comprising the step of determining the expression of cellular protein in the prostate carcinoma by quantifying a protein by an antibody immunologically specific to the cellular protein of Horoszewicz since Horoszewicz states, "This invention relates to the production of and applications for monoclonal antibodies specific for prostatic tumor antigens. More particularly, this invention relates to monoclonal antibodies against non-soluble, membrane associated, organ specific determinants expressed maximally on human normal and neoplastic prostatic epithelium. Monoclonal antibodies capable of reacting with membrane associated surface antigens are of value for the immuno-classification and detection of disease and represent novel agents for immunotherapy (Column 1, lines 18-28)." An ordinary artisan would have been motivated to substitute and combine, within the method of Provari et al., method wherein prostate carcinoma is diagnosed comprising the step of determining the expression of cellular protein in the prostate carcinoma by quantifying a protein by an antibody immunologically specific to the cellular protein of Horoszewicz in order to achieve the express advantages, as noted by Horoszewicz , of monoclonal antibodies capable of reacting with membrane associated surface antigens which are of value for the immuno-classification and detection of disease and represent novel agents for immunotherapy and which

relates to the production of and applications for monoclonal antibodies specific for prostatic tumor antigens.

6. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Provari et al. (Biochemical and Biophysical Research Communication, (August 24, 1995) (Vol. 213(3), pages 861-868) in view of Horoszewicz (U.S. Patent 5,763,202) (June 9, 1998) further in view of Ostanin et al. (The Journal of Biological Chemistry, (March 25, 1994) (Vol. 269(12), pages 8971-8978),

Provari et al. in view of Horoszewicz teach the method of claims 14-20 as described above including quantification of PacP mRNA by its specific hybridization to certain nucleic acid sequences.

Provari et al. in view of Horoszewicz do not teach the method, wherein the specific nucleic acid sequence is at least 15 consecutive nucleotides of M34840.

Ostanin et al. teach the method, wherein the specific nucleic acid sequence is at least 15 consecutive nucleotides of M34840 (Abstract and Page 8971, Column 1, second paragraph of the footnote).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine, within the method of Provari et al. in view of Horoszewicz, the method, wherein the specific nucleic acid sequence is at least 15 consecutive nucleotides of M34840 of Ostanin et al since Ostanin et al. state, "Because of its clinical importance as a prostate tumor marker, human prostatic acid phosphatase (hPAP) is the most

extensively studied of the high molecular weight acid phosphatases (Page 8971, Column 2, first sentence of the second paragraph)." An ordinary artisan would have been motivated to substitute and combine, within the method of Provari et al. in view of Horoszewicz, the method, wherein the specific nucleic acid sequence is at least 15 consecutive nucleotides of M34840 of Ostanin et al. in order to achieve the express advantages, as noted by Ostanin et al., of certain variants of human prostatic acid phosphatase (hPAP) which is the most extensively studied of the high molecular weight acid phosphatases because of its clinical importance as a prostate tumor marker.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703)605-1237.

Arun Chakrabarti,

Patent Examiner,

September 24, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600